

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Girton, et al.

Examiner: Patterson, Marc A.

Serial No.: 10/002,521

Group Art Unit: 1772

Filed: November 1, 2001

Docket: 760-35 CIP/RCE IV

Confirmation No.: 6660

Dated: September 29, 2008

For: NON-EXPANDED POROUS  
POLYTETRAFLUOROETHYLENE  
(PTFE) PRODUCTS AND METHODS  
OF MANUFACTURE

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Dated: September 29, 2008

Signature Barbara Thomas 

**APPEAL BRIEF AND RESPONSE TO NOTIFICATION**  
**OF NON-COMPLIANT APPEAL BRIEF**

Sir:

Appellants resubmit this amended Appeal Brief (originally submitted on September 10, 2008) in response to the Notification of Non-Compliant Appeal Brief dated September 23, 2008.

Appellants have appealed the Examiner's Final Rejection of Claims 2, 3, 21, 22, 24 and 27 dated December 27, 2007 by way of a Notice of Appeal dated May 27, 2007 (with a two-month extension of time). A Response to the Pre-Appeal Brief Request for Review was mailed on July 11, 2008. Therefore, the due date for filing a Brief in support of the appeal is September 11, 2008, with a one-month extension of time, a petition for which is concurrently submitted herewith. This Brief is submitted in support thereof in accordance with the provisions of 37

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C.F.R. § 41.37. As required by 37 C.F.R. §41.37 (a)(2), please charge Deposit Account No. 08-2461 the requisite fee of \$510.00 for submitting a Brief. If additional fees are required, please charge Deposit Account No. 08-2461.

**I. Real Party In Interest**

The subject application is owned by Boston Scientific Scimed, Inc., which is a wholly-owned subsidiary of Boston Scientific Corporation, having acquired rights by way of assignment recorded in the United States and Trademark Office at Reel 018505, Frame 0868.

**II. Related Appeals and Interferences**

No related appeals or interferences are known to Appellants or Appellants' legal representative that will directly affect or be directly affected by or have bearing on the Board's decision in this appeal.

**III. Status of Claims**

Claims 2-4, 11-16, 21-24 and 27 are pending in the application. Claims 1, 5-10, 17-20 and 25-26 have been cancelled.

Claims 2-3, 21, 22, 24 and 27 are finally rejected and on appeal.

Claims 4, 11-16 and 23 are presently withdrawn and not on appeal.

No claims presently stand allowed.

**IV. Status of Amendments**

On March 19, 2008, a Response to an Office Action mailed December 27, 2007 and marked final, was filed requesting reconsideration of the rejections advanced in that December

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27 Action. In an Advisory Action mailed April 17, 2008, the Examiner indicated that the Patent and Trademark Office disagreed with the position advanced by the Response. On May 27, 2008, a Statement in Support of Pre-Appeal Brief Request for Review, Notice of Appeal and Petition for two-month extension of time, was filed requesting reconsideration of the rejection. In the Notice of Panel Decision from Pre-Appeal Brief Review mailed July 11, 2008, the Panel indicated that the application remained under appeal and should proceed to the Board of Patent Appeals and Interferences.

**V. Summary of Claimed Subject Matter**

The present invention as defined by Claim 3 is directed to a vascular graft, which includes an implantable tubular extrudate. The tubular extrudate is extruded in the form of a tube and includes an interpenetrating polymer network with a non-expanded PTFE matrix having no node and fibril structure. The expanded PTFE matrix includes discrete domains of a solid extractable polymeric material distributed therein. The extractable polymeric material is extracted from said matrix, upon exposure to sufficient dissolving medium or degradation temperature, and thus creates pores in the tubular extrudate. The pores permit tissue ingrowth once the extrudate has been implanted.

Further, the present invention as defined by Claim 24 is directed to a PTFE extrudate that includes essentially an interpenetrating polymer network, which includes a non-expanded PTFE resin having no node and fibril structure; and a solid particulate polymeric component, which is incompatible with the non-expanded PTFE resin. The discrete domains of the polymeric component are distributed throughout the non-expanded PTFE resin and are extractable therefrom to create pores in the PTFE resin that will permit tissue ingrowth upon implantation in the body.

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#### **VI. Grounds of Rejection to be Reviewed on Appeal**

The following grounds of rejection are to be reviewed on this Appeal:

I. Whether the Examiner erred in determining that Claims 24 and 27 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Statutory Invention Registration No. H1978 H to Freiburger et al. (hereinafter “Freiburger”).

II. Whether the Examiner erred in determining that Claims 3 and 21-22 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Freiburger in view of U.S. Patent No. 6,190,590 to Randall et al. (hereinafter “Randall”).

III. Whether the Examiner erred in determining that Claim 2 is properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Freiburger in view of Randall and further in view of U.S. Patent No. 6,293,969 to Chuter (hereinafter “Chuter”).

#### **VII. Argument**

I. Claims 24 and 27 are patentable within the meaning of 35 U.S.C. § 103(a) over Freiburger. Appellants respectfully traverse the rejection on the basis that the Examiner has failed to establish a *prima facie* case of obviousness because the reference fails to disclose, teach or suggest the claimed invention.

In the Office Action dated December 27, 2007 and marked final, the Examiner rejected claims 24 and 27 as allegedly being anticipated by Freiburger.

Independent claim 24 relates to a PTFE extrudate that includes essentially “an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure” and “a solid particulate polymeric component which is incompatible with said

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non-expanded PTFE resin.” The polymeric component includes discrete domains distributed throughout the non-expanded PTFE resin. The extraction of these domains creates pores in the PTFE resin. It is these pores that permit tissue ingrowth once the extrudate has been implanted in the body. Claim 27, which adds an additional limitation to claim 24, requires the solid extractable polymeric material to be silicone.

It is respectfully submitted that Freiburger does not form a proper rejection of claims 24 and 27. First, Freiburger is nonanalogous art and is not properly useable in formulating a rejection of the claims herein. Further, the Examiner has misapplied Freiburger and there is no reasonable expectation of success. In addition, Freiburger actually teaches away from the present invention. Finally, the Examiner is utilizing the impermissible hindsight reconstruction to arrive at the present invention and, accordingly, there is no *prima facie* showing of obviousness.

### **1. Freiburger is Nonanalogous Art**

The correct analysis for determining analogous art includes “any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.” KSR International Co. v. Teleflex Inc., 550 U.S. \_\_, \_\_, 82 USPQ2d 1385, 1397 (2007). Following the same reasoning, the MPEP states: “a reference in a field different from that of applicant’s endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his or her invention as a whole.” (MPEP 2141.01(a)).

By definition, if a reference is “nonanalogous art,” it cannot be relied upon as a basis for rejecting an applicant’s claims. As set forth in the case law, there are two criteria for determining whether or not a prior art reference is “analogous”:

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(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.

*In re Clay*, 966 F.2d 656, 658-59, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992); *see also In re Oetiker*, 977 F.2d 1443, 1447, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992); *In re Deminski*, 796 F.2d 436, 442, 230 U.S.P.Q. 313, 315 (Fed. Cir. 1986).

A reference is only "reasonably pertinent" if it is one which "logically would have commended itself to an inventor's attention in considering his problem." *In re Clay*, 966 F.2d at 659.

As the court further explained in *In re Oetiker*:

Patent examination is necessarily conducted by hindsight, with complete knowledge of the applicant's invention, and the courts have recognized the subjective aspects of determining whether an inventor would reasonably be motivated to go to the field in which the examiner found the reference, in order to solve the problem confronting the inventor. We have reminded ourselves and the PTO that it is necessary to consider 'the reality of the circumstances' - in other words, common sense - in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor.

*In re Oetiker*, 977 F.2d at 1447 (citations omitted).

In accordance therewith, MPEP §2141.01(a) similarly expresses the standard that only references that relate to the field of an inventor's endeavor or that are reasonably pertinent to the particular problem to which an inventor is concerned with may be relied upon in formulating a rejection.

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Freiburger is nonanalogous art. Freiburger is outside the inventors' field of endeavor and is not reasonably pertinent to the problem the inventor's wished to solve. As such, Freiburger would not logically be brought to the inventors' attention in considering his invention as a whole.

a. **Freiburger's diaper is outside of the Appellants field of endeavor**

Freiburger relates to monolithic films that have controlled breathability and include high water vapor transmission rate (hereinafter "WVTR") regions and low WVTR regions, and thus, is in a different field of art and directed to an entirely different problem than the present invention. The monolithic films of Freiburger are utilized to create absorbent undergarment or diaper training pants. As such, Freiburger bears no relevance on the prosthesis field of art, nor the inventors' concerns in achieving a porous PTFE material to use in a variety of medical device products without requiring expansion to produce porosity. One of ordinary skill in the medical implantation art would not logically look to the field of absorbent undergarments for guidance with respect to non-expanded porous PTFE extrudates to be used as implantable grafts and stent-products.

Freiburger's absorbable diaper is clearly outside the inventors' field of endeavor, i.e. fluid-tight implantable prostheses having sufficient porosity for tissue ingrowth. Freiburger seeks to solve the breathability problems associated with absorbent garments, which is an entirely different and unrelated problem than the problems addressed by the present invention, i.e. forming a porous PTFE graft without using the standard heat stretching, which creates a node and fibril structure.

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b. Appellants' problem was to obtain a porous PTFE material for use in a medical device without the cost and difficulty associated with conventional expanded PTFE

Appellants were concerned with producing a porous PTFE material to be used in a medical device, without having to partake in the expensive costs and technical difficulties associated with expanding techniques necessary for making the conventional ePTFE.

The overall purpose of the present invention is to create a porous medical device that can be implanted in the body and permit tissue ingrowth without relying on the conventional stretching techniques. The tissue ingrowth process is partially dependent on the ability of blood cells to enter the pores and providing a porous non-expanded PTFE, suitable for implantation in the body. The technical problems associated with the invention do not relate to those associated with absorbent diapers. The present invention overcame these problems by distributing an extractable polymer throughout an IPN and PTFE matrix, then exposing the polymer to a sufficient degradation temperature or dissolving medium to extract it. The resultant product includes pores that permit blood cell penetration, while maintaining a fluid-tight graft.

c. Freiburger's problem was to obtain a diaper with a breathable barrier

Freiburger is nonanalogous art, and thus, not properly useable in formulating a rejection of the claims herein. Freiburger is directed to a monolithic film, which is defined as "non-porous". (Freiburger, col. 3, ll. 10-11). The film has "passages with cross-sectional sizes on a molecular scale formed by a polymerization process." (Freiburger, col. 3, ll. 13-14). The purpose of these passages is so water or liquids can diffuse through the monolithic film "as a result of a concentration gradient" and are re-evaporated into the air. (Freiburger, col. 6, ll. 60-col. 7, ll. 7). However, as stated in Freiburger's specification, "monolithic film provides an absolute barrier to liquids, bacteria, and viruses as no pores are present in the film...no liquid flow is possible unless the film ruptures." (Freiburger, col. 7, ll. 17-30) (emphasis added).

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Freiburger even specifically states that “holes are never intentionally introduced into the film.” (col. 7, l. 52).

The following table illustrates a number of contradictory features between Freiburger and the present invention:

Inventive Composition Characteristics	Freiburger Composition Characteristics
Class 623: Prosthesis, parts thereof, or aid, and accessories thereof	Class: 156: Adhesive bonding and miscellaneous chemical manufacture
Prosthesis implantable in the body	Absorbent garment to be worn outside the body
Pore size of between 5 and 100 microns	Does not have pores
Pore size permits tissue ingrowth in the prosthesis	Passages with cross-sectional sizes on a molecular scale only permit liquid vapors to diffuse through the film
Pores are large enough to allow blood cells to pass through	Passages are a complete barrier to liquids, bacteria and viruses
Includes a solid particulate that is incompatible with the non-expanded PTFE and can be extracted	Holes are never intentionally introduced into the film

As can be seen from the distinctly different systems and concerns illustrated above, there is nothing in Freiburger that would have “logically commended itself” to the present inventors’ attention or anyone skilled in the art of medical devices.

It is clear, therefore, that the inventors herein seeking to satisfy the problems associated with PTFE for use in an implantable prosthesis would not look to Freiburger. As discussed above, Freiburger is concerned with an absorbable diaper with a breathable layer. For all the reasons stated above, Freiburger is not analogous art and cannot be properly relied upon in formulating any rejection herein.

## 2. No Reasonable Expectation of Success

As set forth in MPEP §2143, to establish a *prima facie* case of obviousness, there also must be “a reasonable expectation of success.” The Examiner has misapplied the reference in

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regards to the IPN and thus one of ordinary skill in the art would have no reason to expect to arrive at the present invention based on Freiburger with any degree of success.

The Examiner claims that Freiburger discloses an IPN with discrete domains that are extractable. However, nowhere in Freiburger is extractability disclosed or suggested. Freiburger describes “a polymer/polymer composite combining polydimethyl siloxane and polytetrafluoroethylene in an interpenetrating polymer network.” This combination is the final product of Freiburger and is necessary to achieve the overall purpose. This is in contrast to the present invention, where a polymer is extracted to create a porous PTFE structure that permits tissue ingrowth. The focus of the present invention is to distribute pores or voids throughout the PTFE matrix by using an extractable polymeric component. Without the extractable polymeric component, the IPN would not be porous and would not permit tissue ingrowth. In stark contrast, Freiburger explicitly states that holes are undesirable and “never intentionally introduced into the film.” (Freiburger, col. 7, l. 52). In citing that Freiburger discloses an IPN, the Examiner may have overlooked the fact that Freiburger does not remove the siloxane from the matrix because that would be contrary to the intent of the invention. *See Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448, 230 U.S.P.Q. 416, 419-20 (Fed. Cir. 1986) (holding that a single line should not be taken out of context to show obviousness, but rather, a reference should be considered in its entirety). As such, one of ordinary skill in the art would not look to Freiburger and expect to arrive at the present invention.

The Examiner alleges that one of ordinary skill in the art would have utilized the teachings of Freiburger to modify the pore size in order to have pores that permit tissue ingrowth. Appellants respectfully submit that such an assertion is incorrect. Not only does Freiburger’s final product relate to a wholly different material than the presently claimed invention, the monolithic film discussed in Freiburger acts as a complete barrier to bacteria and viruses. There would be no reason one of ordinary skill in the art would look to Freiburger’s

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non-porous monolithic barrier film, to create a porous PTFE extrudate for implantation in the body, nor could there appear to be any expectation of success in so doing, and thus Freiburger should not be relied upon as a basis for rejection of the present invention.

### **3. Freiburger Teaches Away from the Claimed Invention**

“A prior art reference must be considered in its entirety, i.e. as a whole, including portions that would teach away from the claimed invention.” MPEP §2141.02. When considered as a whole, the disclosure of Freiburger is distinctly different from and even teaches away from the presently claimed invention. The differences between Appellants’ claimed invention and Freiburger go well beyond the fact that they are entirely different technologies. Specifically, Freiburger is directed to an absorbable diaper that is a complete barrier to bacteria and viruses. In contrast, the present invention is directed to an implantable prosthesis that permits tissue ingrowth once placed in the body.

As is well known in the prosthesis art, red blood cells must be allowed to penetrate the porous medical device in order for tissue ingrowth to occur. Tissue ingrowth is necessary for successful implantation of the medical device. Red blood cell penetration is a necessary precondition to tissue ingrowth. Freiburger explicitly states that their diaper is “an absolute barrier” to bacteria and viruses. One of ordinary skill in the art reading Freiburger would not expect that an absolute barrier to bacteria and virus cells would allow for penetration by red blood cells. As such, one of ordinary skill in the art would find that Freiburger clearly teaches away from a pore size that would encourage tissue ingrowth, and thus, the utilization of Freiburger in this rejection is improper.

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**4. Examiner's Conclusion is based on Impermissible Hindsight Reasoning**

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Absent any suggestion in the Freiburger reference leading to the present invention, Appellants maintain that hindsight reconstruction is impermissibly being employed, using the subject application as a template to pick and choose portions of the cited reference which, in turn, are being taken out of context. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellants' disclosure is strictly prohibited. See *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993); See, e.g., *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 57 U.S.P.Q.2d 1164 (Fed. Cir. 2004). The use of such hindsight reconstruction in the absence of any suggestion to combine the references is, however, improper. See *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (noting that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention”); see also M.P.E.P. §2145.X.A.

As stated above, the Examiner alleges that because Freiburger discloses an IPN, Freiburger thus discloses “discrete domains of the silicone distributed throughout the PTFE that are extractable from the PTFE to create pores”. (Office Action at page 3). The Examiner bases this allegation of obviousness on paragraph [0035] of the present specification. The Examiner is simply using the Appellants' specification as a roadmap to piece together the present specification, absent any suggestion in the art to do so. Clearly, one of ordinary skill in the art would not look to the absorbable diaper of Freiburger to arrive at the present invention. The Examiner's impermissible hindsight reconstruction based on the Appellants' specification is strictly prohibited and thus another reason why a rejection based on 103(a) is improper. See M.P.E.P. § 2145.X.A.

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Appellants respectfully submit that claims 24 and 27 are patentable over the cited combination of references. Accordingly, Appellants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

II. Claims 3 and 21-22 are patentable within the meaning of 35 U.S.C. § 103(a) over Freiburger in view of Randall. Appellants respectfully traverse the rejection on the basis that the Examiner has failed to establish a *prima facie* case of obviousness because the references, alone or in combination fail to disclose, teach or suggest the claimed invention.

First, as stated above, Freiburger is nonanalogous art and, thus, not properly useable in formulating a rejection of the claims herein. Second, there is no motivation to combine Freiburger and Randall as suggested by the Examiner. Third, there is no reasonable expectation of success and, accordingly, there is no *prima facie* showing of obviousness based on this hypothetical combination.

#### **1. Freiburger is Nonanalogous Art**

The correct analysis for determining analogous art includes “any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed.” KSR International Co. v. Teleflex Inc., 550 U.S. \_\_, \_\_, 82 USPQ2d 1385, 1397 (2007). Following the same reasoning, the MPEP states: “a reference in a field different from that of applicant’s endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor’s attention in considering his or her invention as a whole.” (MPEP 2141.01(a)).

For all the reasons stated above, Freiburger is nonanalogous art and thus the utilization of Freiburger in the rejection of claims 3, 21 and 22 is improper.

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**2. No Motivation to Combine Freiburger and Randall**

As set forth in MPEP §2143.01, “Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.”

As the court further explained in *In re Paulsen*:

. . . we have been guided by the well settled principles that the claimed invention must be considered as a whole, multiple cited prior art references must suggest the desirability of being combined, and the references must be viewed without the benefit of hindsight afforded by the disclosure.

*In re Paulsen*, 30 F.3d 1475, 1482, 31 U.S.P.Q.2d 1671, 1676 (Fed. Cir. 1994).

Contrary to the Examiner’s assertions, there is no motivation to combine Freiburger and Randall. As stated in detail above, Freiburger is directed to an absorbent garment. Randall is directed towards a graft that is made of microporous expanded polytetrafluoroethylene (ePTFE). One of ordinary skill in the art would not look to an absorbent garment, to be worn outside of the body and an ePTFE graft to create the presently claimed invention.

Expanded PTFE is conventionally formed by taking an extruded tube or sheet of PTFE and stretching it to form a node and fibril structure to create a porous structure that may be used for implantation in the body. It is well known that porous expanded PTFE has distinct advantages over non-expanded PTFE, because the former permits ingrowth by the body and better assimilation and acceptance long term (patency) as an implant. This is extremely important in cases where the implant is a blood vessel. The spaces between the nodes and fibrils allow the porous, fibrillated PTFE to assimilate well into the body. Thus, expanded (or fibrillated) PTFE is commonly used as an implant material.

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The Examiner has provided no reason why one of ordinary skill in the art would combine the monolithic film of an absorbable diaper that includes an IPN with an ePTFE graft to arrive at the present invention. Moreover, the Examiner has provided no reason why one of skill in the art would combine the IPN of Freiburger and an ePTFE graft of Randall to arrive at a non-expanded PTFE graft with no node and fibrils.

As stated above, the present invention distributes pores or voids throughout the PTFE matrix by using an extractable polymeric component. Although Freiburger discloses a monolithic film with an IPN, it is explicitly stated that holes are “never intentionally introduced into the film.” As such, it does not follow that one of ordinary skill in the art would then look to Randall, a graft reference that utilizes expanded PTFE, to arrive at the present invention, a non-expanded PTFE matrix with no node and fibril structure.

### **3. No Reasonable Expectation of Success**

As stated above and provided in MPEP §2143, to establish a prima facie case of obviousness, there also must be “a reasonable expectation of success.” Not only is there no suggestion to combine the teachings of Freiburger and Randall, there is no reasonable expectation of success that the hypothetical combination would work. As set forth above, Freiburger and Randall relate to completely different products. *See In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991) (explaining that “the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure”).

Not only is there no motivation to combine Freiburger and Randall, there is incentive not to combine them. When Freiburger is considered for its whole teaching, it would provide no direction toward solving Appellants’ problem. Randall utilizes ePTFE, which, as stated above, is the expense and difficulty Appellants sought to avoid. One of skill in the art would have no

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incentive to combine an absorbent diaper with an ePTFE graft to solve the problems associated with ePTFE grafts.

Appellants' claim 3 specifically recites that the non-expanded PTFE has "no node and fibril structure." Rather than use the traditional process of expanding the PTFE to create pores by the formation of a node and fibril structure, the present invention creates pores in non-expanded PTFE by first creating an IPN which contains a polymer that can be removed, and then removing the polymer to leave behind pores in the PTFE. This is distinctly different from Freiburger and Randall. Nowhere in either reference is it disclosed, taught or suggested to use an IPN of non-expanded PTFE having no node and fibril structure and another extractable polymer. Accordingly, Randall on its own lacks any teaching or suggestion of an IPN as recited in Claim 3 or the use of non-expanded PTFE in creating such an IPN. In fact, Randall suggests the opposite, i.e. no IPN and an ePTFE, which the ordinary person skilled in the art would understand to have a node and fibril structure because it is expanded. Thus, Randall fails to fails to render claim 3, and any that depend therefrom, *prima facie* obvious.

Randall fails to overcome the deficiencies of Freiburger. As none of the cited references (alone or in combination) would reasonably suggest the present invention to one of ordinary skill in the art, it is respectfully submitted that the rejection under 35 U.S.C. §103(a) is unsustainable.

#### **4. Examiner's Conclusion is based on Impermissible Hindsight Reasoning**

As stated above, there is no reason to combine Freiburger and Randall and there is nothing in Freiburger or Randall that would suggest any degree of success at obtaining the present invention. Thus, it is clear that the Examiner has again utilized hindsight reconstruction to arrive at claims 3, 21 and 22. Absent any suggestion in the Freiburger or Randall references leading to the present invention, Appellants maintain that hindsight reconstruction is

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impermissibly being employed, using the subject application as a template to pick and choose portions of the cited references which, in turn, are being taken out of context.

The Examiner alleges that one of ordinary skill in the art would “recognize the advantage of providing for the graft of Randall et al in Freiburger et al, which comprises PTFE, depending on the desired cuffing of the end product.” (Office Action, at page 3). The Examiner further alleges that it “would have been obvious for one of ordinary skill in the art at the time Applicant’s invention was made to have provided for a vascular graft in Freiburger et al in order to obtain a vascular graft having a cuffed graft as taught by Randall et al.” (Office Action, at page 4). The Examiner also alleges that, even though Freiburger does not disclose pore size, it would be obvious “for one of ordinary skill in the art to select a solid particulate, therefore of a desired size, as solid particulate and liquid are physical states of silicone.” (Office Action, at page 4).

As stated in detail above, Freiburger is directed to an absorbable diaper. Nowhere in Freiburger is it disclosed, taught or suggested to utilize an implantable tubular extrudate that permits tissue ingrowth. The Examiner simply picked a sentence of Freiburger relating to an IPN, which is a part of the breathable film associated with the absorbable diaper and not something one of skill in the art would implant in the body. The Examiner then combined this sentence of Freiburger with the graft of Randall to arrive at the present invention. One of skill in the art, reading Freiburger in its entirety, would not combine it with Randall. Thus, the Examiner has impermissibly utilized hindsight reconstruction to arrive at the present invention and thus this rejection is improper.

Appellants respectfully submit that claims 3 and 21-22 are patentable over the cited combination of references. Accordingly, Appellants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

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III. Claim 2 is patentable within the meaning of 35 U.S.C. § 103(a) over Freiburger in view of Randall and further in view of Chuter. Appellants traverse the rejection.

The above-argument equally applies herein as claim 2 depends from independent claim 3. Specifically, Freiburger fails to teach or suggest a vascular graft of claim 3 that includes a radially distensible stent positioned axially about said tubular extrudate.

As stated in detail above, neither Freiburger nor Randall disclose, teach or suggest an IPN with non-expanded PTFE matrix having no node and fibril and an extractable polymeric component that is to be implanted in the body and permits tissue ingrowth. Chuter was merely cited for its disclosure of a porous PTFE comprised in first and second stents. However, nowhere in Chuter is an IPN that includes a non-expanded PTFE matrix having no node and fibril structure disclosed, taught or suggested. Chuter fails to overcome the deficiencies of Freiburger and Randall as above argued. Therefore, withdrawal of the rejection is requested and proper.

Appellants respectfully submit that claim 2 is patentable over the cited combination of references. Accordingly, Appellants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

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**D. Conclusion**

For the reasons set forth above, Freiburger, Randall and Chuter fail to disclose, teach or suggest a vascular graft or PTFE extrudate as recited in the claims. In conclusion, claims 2-3, 21, 22, 24 and 27 are patentable.

Favorable action is earnestly solicited and a finding of patentability of claims 2-3, 21, 22, 24 and 27 is respectfully requested.

Respectfully submitted,



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### **VIII. Claims Appendix**

2. The vascular graft of claim 3 further including a radially distensible stent positioned axially about said tubular extrudate.
3. A vascular graft comprising:  
an implantable tubular extrudate, said tubular extrudate being extruded in the form of a tube, comprising an interpenetrating polymer network comprising a non-expanded PTFE matrix having no node and fibril structure, said matrix having distributed therein discrete domains of a solid extractable polymeric material, wherein upon exposure to sufficient dissolving medium or degradation temperature, said extractable polymeric material is extracted from said matrix to create pores in said tubular extrudate which upon implantation permit tissue ingrowth.
21. The vascular graft according to Claim 3, wherein said extractable polymeric material comprises silicone.
22. The vascular graft according to Claim 3, wherein said extractable polymeric material is particulate and has a particle size of about 5 to 100 microns.
24. A PTFE extrudate consisting essentially of:  
an interpenetrating polymer network comprising a non-expanded PTFE resin having no node and fibril structure; and  
a solid particulate polymeric component which is incompatible with said non-expanded PTFE resin,

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wherein discrete domains of said polymeric component are distributed throughout said non-expanded PTFE resin and are extractable therefrom to create pores in said PTFE resin which upon implantation permit tissue ingrowth.

27. The PTFE extrudate according to Claim 24, wherein said solid extractable polymeric material comprises silicone.

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**IX. Evidence Appendix**

There were no declarations or other evidence submitted during the prosecution of this application.

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**X. Related Proceedings Appendix**

Appellants are not aware of any related proceedings.